SUBCOMMITTEE ON HEALTH HEARING ENTITLED, "H.R. 5998, THE 'PROTECTING CHILDREN'S HEALTH COVERAGE ACT OF 2008'"

Mr. Chairman, I commend you and Rep. Shea-Porter for introducing H.R. 5998, the "Protecting Children’s Health Coverage Act of 2008”.

SUBCOMMITTEE ON HEALTH HEARING ENTITLED, "DISCUSSION DRAFT OF THE 'FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT' LEGISLATION: DEVICE AND COSMETIC SAFETY PROVISIONS"
May 14, 2008

Mr. Chairman, I appreciate your diligence in holding this series of legislative hearings. They have focused on what resources and authorities the Food and Drug Administration (FDA) needs to adequately protect the public health. The third and final hearing today will focus on the device and cosmetic safety provisions of the discussion draft.

The same issues that challenge FDA’s ability to properly oversee food and drugs in an increasingly global marketplace also plague the agency’s ability to regulate medical devices and cosmetics.

As stated in the 2007 FDA Science Board report on FDA’s ability to carry out its mission, in the case of medical devices, the report noted that, “due to constrained resources and lack of adequate staff, FDA is engaged in reactive regulatory priority setting or a fire-fighting regulatory posture instead of pursuing a culture of proactive regulatory science.”

This was confirmed in recent testimony of the Government Accountability Office (GAO) before the Subcommittee on Oversight and Investigations, which found that FDA was not able to make the required inspection every two years of domestic facilities where the highest-risk medical devices are manufactured. We understand that currently FDA is only able to inspect medium-risk medical device facilities once every five years and high-risk device facilities only once every three years.

And the number of inspections for foreign producers is much worse. GAO estimated that FDA inspects foreign manufacturers of Class II devices only every 27 years and foreign class III manufacturers every 6 years. Despite the fact that there are more registered device manufacturers in China than in any other foreign country, Chinese firms can expect FDA

to visit only once every 50 years.

And while
cosmetics currently represent 9 percent of FDA-regulated products imported into the United States, the number of these imports is growing. In spite of a small budget increase last year, the FDA Office of Cosmetics and Colors has been unable to keep pace with the increasing numbers of foreign cosmetic products.

We will hear from two FDA officials today who I hope will be forthright in their testimony about the needs of the Agency. We in Congress do a better job for American consumers if we receive frank and truthful testimony from the people vested with regulatory responsibility.

I want to commend those in the device and cosmetic industry who have stepped forward to work with us to strengthen FDA. As we start this effort, however, we must all keep in mind the dire straits at FDA and understand that the Federal budget alone cannot support the growing demands on the Agency. Industries that benefit from a global marketplace must also share responsibility for the safety of products they sell to American consumers.

Lastly, I thank
the consumer groups and other stakeholders who recognize the crisis at FDA and who have committed to work with us on this effort. Following the conclusion of today’s hearing, I intend to begin work immediately with the Committee’s Ranking Member, Mr. Barton, and other Members of the Committee to build a strong, bipartisan piece of legislation.

Prepared by the Committee on Energy and Commerce

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